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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Dazé, Board Member
Hank Hough, Board Member
Ken Schell, PharmD, Board Vice-President

LEGISLATION REPORT

4. BOARD SPONSORED LEGISLATION – FOR INFORMATION ONLY

a. Omnibus Provisions

At the January 2007 Board Meeting, the board voted to include all of the following provisions as omnibus provisions for 2007. This language has not yet been incorporated into the Committee's Bill. According to the committee's consultant, these provisions will be in print by the end of May. Copies of the exact language follow in Attachment D-4a.

- **Sections 4162 and 4162.5**
  Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.
- **Sections 4314 and 4315**
  Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.
- **Section 4084**
  To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
- **Sections 4160(f) – 4161(k)**
  Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.
- **Section 4208**
  Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

b. Proposed changes to AB 2986 (Chapter 286, Statutes of 2006)

At the January 2007 Board Meeting, board members voted to pursue changes to current CURES reporting requirements.

Last year AB 2986 changed the reporting requirement for CURES, expanded reporting to include Schedule IV controlled substances, and added elements that must be entered into CURES (e.g., the patient phone number and number of refills). Specifically, C-IIs, IIIs, and IVs now must be submitted weekly to Atlantic Associates.

However, staff is also recommending a specific amendment to mandate a January 1, 2008, "drop dead date" for aggressive enforcement, as well as a requirement for prescribers to use of the new security prescription forms that contain the new data fields, also by January 1, 2008 (essentially by making the current security forms obsolete).

A draft of the proposed revisions is included in Attachment D-4b. Staff at the Department of Justice supports this proposal.

The board will monitor compliance with AB 2986 requirements during 2007 inspections and is encouraging pharmacies to work with their software vendors to ensure compliance as quickly as possible.

5. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction - Board Action Required

Provided in this packet are copies of bills impacting the practice of pharmacy or the board's jurisdiction. These bills were reviewed at the April 3, 2007 Legislation and Regulation Committee meeting. Below is a brief summary of each proposal as well as the committee's recommendation. Unfortunately due to time constraints at the committee meeting, not all bills presented for this meeting have a committee recommendation. The board can make a motion on any of these proposals. Bill analysis and copies of each bill are included in Attachment D-5. A listing of each bill, author and committee recommendation is provided in advance of the bill analysis. Copies of any amended bills and updated bill analysis will be provided at the board meeting.

a. AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

This proposal would allow for the use of General Fund money to purchase needles for NEP programs.

Committee Recommendation: Watch

b. AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

This proposal would prevent all health care practitioners from including a "gag clause" in a civil action.

Committee Recommendation: Support

c. AB 501 (Swanson) Pharmaceutical Devices: Hypodermic Needle and Syringe Disposal

This proposal would require every pharmaceutical company whose product requires the use of prefilled syringe, prefilled pen needle or other prefilled injection device to provide a method for California patients to dispose of the device.

Committee Recommendation: Support

d. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would standardize the licensing requirements for ambulatory surgical centers.

Committee Recommendation: Support

e. AB 851 (Brownley) Prescription Drugs: Informational Insert

This proposal would require the inclusion of a large font informational insert with all prescription medications that could adversely interact with alcohol and/or other prescribed or over-the-counter medications.

Committee Recommendation: No Position

f. AB 865 (Davis) State Agencies: Live Customer Service Agents

This proposal would require all state agencies to answer public telephone lines within 10 rings.

Committee Recommendation: Neutral

g. AB 1025 (Bass) Professions and Vocations: Denial of Licensure

This proposal would prohibit the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside or for an arrest where a final disposition has not occurred within one year.

Committee Recommendation: None

h. AB 1137 (Eng) Boards and Commissions

This proposal would direct the Joint Committee on Boards, Commissions, and Consumer Protection to consider during its review of a regulatory program, if the functions would be more effective with a single executive officer.

Committee Recommendation: None

i. AB 1276 (Karnette) Pharmacies: Prescription Containers: Labels

This proposal would require the prescription label to include the intended use for the medication if noted on the prescription by the prescriber.

Committee Recommendation: None

j. AB 1399 (Richardson) Pharmacies: Prescription Labels

This proposal would require a pharmacy to provide a prescription label that is readable by an assistive technology device if requested.

Committee Recommendation: None

k. AB 1587 (De La Torre) Personal Information: Pharmacy

This proposal would make exemptions to the definition of marketing materials.

Committee Recommendation: None

l. SB 472 (Corbett) Prescription Drugs: Labeling Requirements

This proposal is still in the drafting phase, but the intent is to ensure standardization of prescription labels.

Committee Recommendation: None

m. SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program

This proposal would establish a scholarship and loan repayment program for pharmacy technicians and require all pharmacy technicians as well as pharmacies to contribute $10.00 at the time of renewal.

Committee Recommendation: None

n. SB 809 (Ashburn) Nurse Practioners

This proposal would expand the scope of practice for nurse practitioners to include, among other things, the independent prescribing and dispensing of medications.

Committee Recommendation: None

o. SB 822 (Aanestad) Psychology: Scope of Practice

This proposal would create a prescribing psychologist certification to allow the prescribing of limited medications by a certified psychologist.

Committee Recommendation: None

p. SB 963 (Ridley-Thomas) Regulatory Boards: Termination

This proposal would remove the Department of Consumer Affairs as the automatic successor in the event a board is "sunsetted."

Committee Recommendation: None

q. SB 966 (Simitian) Pharmaceutical Drug Disposal

This proposal would require pharmacies to accept then dispose of returned unused medications.

Committee Recommendation: None

r. SB 993 (Calderon) Psychologists: Scope of Practice: Prescribing Drug

This proposal would expand the scope of practice for psychologists to include prescribing medications for specially trained and certified psychologists.

Committee Recommendation: None

6. *Other Legislation – For Information Only*

The bills listed below are included for information only as they may be of interest to the board or industry, but may not directly impact the practice of pharmacy or the board's jurisdiction. Copies of the proposals are included in Attachment D-6.

a. AB 14 (Laird) Discrimination: Civil Rights Act of 2007
b. AB 64 (Berg) Uniform Emergency Volunteer Health Practitioners Act
c. AB 106 (Berg) Immunizations
d. AB 329 (Nakanishi) Chronic Diseases: Telemedicine
e. AB 374 (Berg) California Compassionate Choices Act
f. AB 436 (Salas) Health Insurance Portability and Accountability Act of 2001
g. AB 555 (Nakanishi) Healing Arts: Medical Records
h. AB 703 (Ruskin) Social Security Numbers
i. AB 1302 (Horton) Health Insurance Portability and Accountability Act of 2001
j. ACR 9 (Dymally) Legislative Task Force on Substance Abuse
k. SB 254 (Aanestad) Health Facilities: Licensure
l. SB 907 (Calderon) Physicians and Surgeons: Referrals

Attachment D-4a

Omnibus language

Board of Pharmacy
2007 Omnibus Bill Proposed Language

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device

Amend Section 4084 of the Business and Professions Code, to read:

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.
(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
(f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

B&P 4162 & 4162.5 Wholesaler License Surety Bond Requirements

Amend Sections 4162 and 4162.5 of the Business and Professions Code to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).
(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).
(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one

hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, ~~2011~~ 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).
(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, ~~2011~~ 2015, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to

this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

B&P 4160 Wholesaler License Required

Amend Section 4160 & 4161 of the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler~~. A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(g) This section shall become operative on January 1, 2006.

4161 a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.~~ A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

B&P 4208 Intern Pharmacist License

Amend Section 4208 of the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.
(c) An intern pharmacist shall notify the board within 30 days of any change of address.
(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) Persons who have not completed experience requirements necessary to be eligible for the licensure examination may have their intern license extended for a period of up to two years at the discretion of the board if able to demonstrate their inability to exercise the privileges of the intern license during the initial license period.

Attachment D-4b

Proposed Changes to AB 2986

Board of Pharmacy
Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)

CURES REPORTING

SECTION 1. Section 11162.1 of the Health and Safety Code is amended to read:
11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:
(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
(3) A chemical void protection that prevents alteration by chemical washing.
(4) A feature printed in thermo-chromic ink.
(5) An area of opaque writing so that the writing disappears if the prescription is lightened.
(6) A description of the security features included on each prescription form.
(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:
1–24
25–49
50–74
75–100
101–150
151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, telephone number, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.
(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
(11) The date ~~of origin of~~ the prescription was written for the patient by the prescriber.
(12) A check box indicating the prescriber's order not to substitute.
(13) An identifying number assigned to the approved security printer by the Department of Justice.
(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.
(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).
(2) Forms ordered pursuant to this subdivision shall have preprinted on the form:

(A) tThe name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber ~~and~~
(B) tThe name, address, category of licensure, and license number of the licensed health care facility, the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons. ~~preprinted on the form.~~
(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, telephone number, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and be maintained in the health facility for three years.
(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
~~(d) This section shall become operative on July 1, 2004.~~

SEC. 2. Section 11164 of the Health and Safety Code is amended to read:
11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the patient's name ~~of the ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription ~~is a~~ is being filled initially or as ~~first-time request or~~ a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:
11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.
(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.
(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy shall provide the following information to the

Department of Justice on a weekly basis each Monday for the preceeding week (Monday through Sunday), and in a format specified by the Department of Justice:
(1) Full name~~,~~ and address~~, and the telephone number~~ of the ~~ultimate user~~ patient or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ~~ultimate user~~ patient.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered.
(8) Whether the drug was dispensed or as the original of a prescription or as a refill ~~of a prescription or as a first-time request~~.
(9) Date ~~of origin of~~ the prescription was written or ordered for the patient.
(10) Date of dispensing of the prescription.
~~(c) This section shall become operative on January 1, 2005.~~

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:
11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual patient under his or her care based on data contained in CURES.
(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual patient based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the ~~individual~~ patient.
(c) The history of controlled substances dispensed to ~~an individual~~ a patient based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 5. Section 11190 of the Health and Safety Code is amended to read:
11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, and the telephone number of the patient ~~ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Number of refills ordered.
(G) Whether the drug was dispensed as a refill of a prescription or as ~~a first-time~~ the original of a prescription request.
(H) Date ~~of origin of~~ the prescription was written or ordered for the patient by the prescriber.
(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.
(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user.
~~(d) This section shall become operative on January 1, 2005.~~
(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.
(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Attachment D-5

Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

- *Check List*
- *Bill Analysis*
- *Bill*

Bill Number	Author	Topic	Committee Recommended Position	Board Position
AB 110	Laird	Drug Paraphernalia: Clean Needle and Syringe Exchange Projects	Watch	
AB 249	Eng	Healing Arts: Settlement Agreements	Support	
AB 501	Swanson	Pharmaceutical Devices	Support	
AB 543	Plescia	Ambulatory Surgical Centers: Licensure	Support	
AB 851	Brownley	Prescription Drugs: Informational Insert	None	
AB 865	Davis	State Agencies: Live Customer Service Agents	Neutral	
AB 1025	Bass	Professions and Vocations: Denial of Licensure	None	
AB 1137	Eng	Boards and Commissions	None	
AB 1276	Karnette	Pharmacies: Prescription Containers: Labels	None	
AB 1399	Richardson	Pharmacies: Prescription Containers	None	
AB 1587	De La Torre	Personal Information: Pharmacy	None	
SB 472	Corbett	Prescription Drugs: Labeling Requirements	None	
SB 615	Oropeza	Pharmacy Technicians: Scholarship Fund	None	
SB 809	Ashburn	Nurse Practitioners	None	
SB 822	Aanestad	Psychology: Scope of Practice	None	
SB 963	Ridely-Thomas	Regulatory Boards: Termination	None	
SB 966	Simitian	Pharmaceutical Drug Disposal	None	
SB 993	Calderdon	Psychologists: Scope of Practice: Prescribing Drugs	None	

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 110 VERSION: As introduced January 5, 2007

AUTHOR: LAIRD SPONSOR: Drug Policy Alliance Network
San Francisco Aids Foundation

RECOMMENDED POSITION: Watch

SUBJECT: Drug paraphernalia: clean needle and syringe exchange projects

EXISTING LAW:

1. Permits a needle exchange program (NEP) in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

2. Requires a city and county, or a county, or a city with or without a health department that authorizes a NEP, to authorize the exchange of clean hypodermic needles and syringes, as part of a network of comprehensive services, including treatment services.

3. Prohibits providers participating in an authorized NEP from being subject to criminal prosecution for possession of needles or syringes during participation in a NEP.

4. Requires local government, local public health officials, and law enforcement to be given the opportunity to comment on syringe exchange programs on an annual basis. Requires the public to be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of syringe exchange programs are addressed and mitigated. Requires the health officer of the participating jurisdiction to present annually at an open meeting of the board of supervisors or city council a report detailing the status of NEPs including, but not limited to, relevant statistics on blood-borne infections associated with needle sharing

activity. Requires law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public to be afforded ample opportunity to comment at this annual meeting, as specified.

THIS BILL:

1. Makes a number of findings and declarations related to the continuing spread of acquired immune deficiency syndrome (AIDS) and blood-borne hepatitis, the relationship between injection drug use and HIV/AIDS and hepatitis, the reduction in the transmission of HIV and hepatitis resulting from NEPs, and the need for NEPs to purchase adequate supplies of sterile hypodermic needles in order to further reduce HIV and hepatitis transmission.

2. Permits a public entity that receives General Fund money from Department of Public Health (formerly DHS) for HIV prevention and education to use that money to support NEPs that are authorized by the public entity, as specified.

3. Permits the money to be used for, but not be limited to, the purchase of sterile hypodermic needles and syringes.

4. Requires funds allocated for the purchase of sterile hypodermic needles and syringes to be based upon epidemiological data as reported by the health jurisdiction in its local HIV prevention plan submitted to DPH.

5. Requires local health officers in jurisdictions with NEPs to include information on the use of public funds for NEPs in their annual report detailing the status of the project to the board of supervisors or city council.

AUTHOR'S INTENT

According to the author, the U.S. government prohibits the use of federal funds to support the purchase of sterile hypodermic needles and syringes by Needle Exchange Programs (NEPs) and to date the state has not permitted the use of its funds for the purchase of sterile hypodermic needles and syringes. The ability of NEPs to purchase an adequate supply of sterile hypodermic needles and syringes is essential to California's ability to further reduce the transmission of HIV and other blood-borne diseases and relieve the public cost for the care and treatment of those diseases.

The use of state General Fund to purchase clean needle and syringes for NEPs is not unprecedented. Eleven states currently expend these funds for this purpose (Connecticut, Hawaii, Massachusetts, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin). This bill would substantially aid local efforts to reduce the rate of HIV transmission through injection drug use in California by authorizing the use of state funds for the purchase of clean hypodermic needles and syringes. Any funds that would be expended for clean needles and syringes come from existing appropriations for state HIV prevention funds. Accordingly, this bill does not increase funding and will, in effect, make counties prioritize how they will expend prevention funds. One of these choices may be to purchase needles and syringes, which could result in significant savings for state funded health programs.

PRIOR HISTORY/RELATED BILLS

AB 547 (Berg and Richman) Chapter 692, Statutes 2005 - authorized clean NEPs in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county; the city council, the mayor, and the local health officer of a city with a health department; or, the city council and the mayor of a city without a health department. No board position

AB 1597 (Laird) of 2005 contained provisions substantially similar to this bill - Governor Schwarzenegger vetoed AB 1597, stating "authorizing the use of state funds to purchase syringes, without appropriate local controls, including mechanisms for input from local law enforcement, and protections against the use of state funds to supplant private or local resources is not prudent." No board position

AB 2076 (Laird) of 2006 contained provisions substantially similar to this bill - held on the Assembly Floor after passing both houses of the Legislature. No board position.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

SUPPORT AND OPPOSITION:

Support: AIDS Project Los Angeles
America Federation of State, County and Municipal Employees; AFL-CIO
California Hospital Association

California Opioid Maintenance Providers
California State Association of Counties
City of Moreno Valley
Drug Policy Alliance Network
Friends Committee on Legislation
Lamda Letters Project
San Francisco AIDS Foundation
Santa Clara County Board of Supervisors
Southern California HIV Advocacy Coalition

Oppose: California Narcotic Officers' Association

HISTORY:

2007
Mar. 28 In committee: Set, first hearing. Referred to APPR. suspense file.
Mar. 7 From committee: Do pass, and re-refer to Com. on APPR. Re-referred.
(Ayes 12. Noes 5.) (March 6).
Feb. 1 Referred to Com. on HEALTH.
Jan. 6 From printer. May be heard in committee February 5.
Jan. 5 Read first time. To print.

Revised April 10, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 249 VERSION: As introduced February 1, 2007

AUTHOR: Eng SPONSOR: Author

RECOMMENDED POSITION: Support

SUBJECT: Licensees: healing arts: settlement agreements

EXISTING LAW:

1. Prohibits a physician or surgeon from including a provision in a civil settlement that prohibits the other party from contacting or cooperating with the Medical Board.
2. Prohibits a physician or surgeon from including a provision in a settlement for a civil action that requires the other party from filing a complaint with the Medical Board.
3. Prohibits a physician or surgeon from including a provision in a settlement that requires the other party to withdraw a complaint from the Medical Board.
4. Declares that such provisions is void as against public policy.
5. Specifies that a physician or surgeon who violates the section is subject to disciplinary action.

THIS BILL WOULD:

1. Expand the above prohibitions to apply to all licensees and entities or persons acting as an authorized agent of a licensee licensed under Division 2 of the Business and Professions Code.

AUTHOR'S INTENT

This bill is intended to close a loophole in current law that allows a healthcare professional licensed by DCA to prohibit a consumer who settles a civil suit from also filing a complaint or cooperating with the licensee's regulator. This bill is modeled on an existing statute that prohibits physicians and surgeons from including such clauses in civil settlements arising from his or her practice.

According to the author, "The state has created regulatory agencies to license healthcare professionals in order to protect patients, but those same healthcare practitioners can use gag clauses in malpractice settlements to prevent the licensing agency from finding out about their abuses. That makes absolutely no sense. Licensed healthcare professionals should not be able to misuse the civil justice system to conceal evidence of misconduct from their regulators."

PRIOR HISTORY/RELATED BILLS

AB 320 (Correa) of 2004 would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed. The governor's message is as follows: "I am returning Assembly Bill 320 without my signature as it further erodes the ability to do business in California by creating more uncertainty regarding litigation and litigation costs.

This bill prohibits all businesses and professions licensed under the Department of Consumer Affairs (DCA) from inserting gag clauses in civil suits settled with customers.

When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties. Often settlements are reached when the cost of settlement is less than the cost of defense even if a party believes they have not erred, it often makes economic sense to settle.

Under this bill a party who agrees to a civil settlement, could still file a complaint with a regulatory agency subjecting the licensee to double jeopardy. Even after the resolution of a civil suit, this bill could still require a licensee to a second adjudication before a regulatory body.

The policy implications of this bill does not further the goal of making California more business friendly, therefore, I cannot support this bill. The board had a support position on this bill."

AB 446 (Negrete McLeod) of 2005, would have prohibited all DCA licensed professionals from including a gag clause in a civil settlement. This bill was vetoed by the governor with the following message - - "I vetoed a similar bill last year because of the negative effect it would have had on the California economy. This bill further erodes the ability to do business in California by creating more uncertainty regarding litigation by prohibiting any licensee or professional overseen by the Department of Consumer Affairs from including in a civil settlement agreement a

provision that prohibits the other party from contacting or filing a complaint with the regulatory agency. When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties." The board had a support position on this bill.

AB 2260 (Negrete McLeod), Chapter 565, Statutes of 2006, prohibits physicians and surgeons licensed by the Medical Board from including a gag clause in a civil settlement agreement. The board did not take a position on this bill.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact. Any minor fiscal impact could be absorbed within existing resources.

SUPPORT AND OPPOSITION:

Support: California Nurses Association
Center for Public Interest Law

Opposition: None on file

HISTORY:

2007
Mar. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 9. Noes 1.) (March 27).
Mar. 6 From committee: Do pass, and re-refer to Com. on JUD. Re-referred. (Ayes 10. Noes 0.) (March 6).
Feb. 20 Referred to Coms. on B. & P. and JUD.
Feb. 2 From printer. May be heard in committee March 4.
Feb. 1 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 501 VERSION: As introduced February 20, 2007

AUTHOR: Swanson SPONSOR: Alameda County Board of Supervisors

RECOMMENDED POSITION: Support

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers
   a. Any container used for collection of solid waste, recyclable materials for greenwaste
   b. Any container used for the commercial collection of solid waste or recyclable materials from a business establishment
   c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home generated sharps waste shall be transported only in a sharps container, or other container approved by the enforcement agency as managed by one of the following:
   a. A household hazardous waste facility
   b. A "home generated sharps consolidation point"
   c. A medical waste generator's facility
   d. A facility though the use of an approved medical waster mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of self-inject prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the US Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Require every pharmaceutical company whose product is dispensed through a prefilled syringe, prefilled pen needle or other prefilled injection device shall provide each person in this state with a method to safely dispose of the device.
4. Require that if the person receives the device as part of a starter kit, the pharmaceutical company shall make available to the person, at no additional cost, either a postage pre-paid mail back sharps container or a coupon to obtain such a container or provide the person with a distribution point chosen by the pharmaceutical company.
5. Require the pharmaceutical company to make available, at no additional charge and through an annually renewable program, postage prepaid, mail back sharps containers to any person who uses the pharmaceutical company's product.
6. Define "coupon," "patient starter kit" and "sharps container."

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 –Prohibits, as of January 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home generated-sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact on its operations.

HISTORY:

2007
Mar. 22 Referred to Com. on HEALTH.
Feb. 21 From printer. May be heard in committee March 23.
Feb. 20 Read first time. To print..

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 543 VERSION: As amended March 28, 2007

AUTHOR: Plescia SPONSOR: CA Ambulatory Surgery Assoc.

RECOMMENDED POSITION: Support

SUBJECT: Ambulatory surgical centers: licensure

EXISTING LAW:

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale unless licensed by the board.
3. Defines the licensing requirements for the board to issue a clinic license to an ambulatory surgery center.

THIS BILL WOULD:

1. Change the name "surgical center" to "ambulatory surgical center."
2. Modify the licensing requirements for a board issued clinic license for an ambulatory surgical center to include:
   - licensure by the DHS under 1204 of the Health and Safety Code
   - accreditation by an approved agency
   - or certification to participate in the Medicare Program.

   This license would allow the clinic to purchase drugs at wholesale for administration or dispensing.
3. Develop standard licensing requirements for the DHS to license ambulatory surgery centers. These requirements are phased in over a period of time.

AUTHOR'S INTENT

The sponsor states that this bill is intended to standardize the licensing requirements for ambulatory surgical clinics. Additional amendments to the existing language will also be made to ensure a consistent and comprehensive set of state-specific licensure requirements for ambulatory surgical centers as required by the DHS.

PRIOR HISTORY/RELATED BILLS

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in the se facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner."

The board had no position on this bill.

FISCAL IMPACT:

The sponsor believes that 400 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications should all eligible facilities choose to pursue licensure with the board. In addition the board would require an additional 0.5 inspector to complete routine inspections and complaint investigations.

COMMENTS:

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However there is no requirement that an ambulatory surgical center must be licensed by the DHS to operate. The unintended consequence is that approximately 400 – 500 ambulatory surgical centers do not qualify for licensure as a clinic by the board, but would under this bill.

There are currently four approved accreditation agencies:

- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)

- Joint Commission of Accreditation of Healthcare Organizations (JCAHO)
- The Institute for Medical Quality (IMQ)

HISTORY:

2007
Mar. 29 Re-referred to Com. on HEALTH.
Mar. 28 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 1 Referred to Com. on HEALTH.
Feb. 22 From printer. May be heard in committee March 24.
Feb. 21 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 851 VERSION: AS INTRODUCED February 22, 2007

AUTHOR: BROWNLEY SPONSOR: AUTHOR

RECOMMENDED POSITION: None

SUBJECT: PRESCRIPTION DRUGS: INFORMATIONAL INSERT

EXISTING LAW:

1. Requires a pharmacist to inform a patient orally or in writing of the harmful side effects of a prescription drug if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug provided may impair a person's ability to drive a motor vehicle. Relevant drug classifications are detailed in CCR 1744.
2. States that the notification requirement does not apply to drugs furnished in conjunction with treatment or emergency services provided in a health facility.
3. States that a health facility must establish and implement a written policy to ensure each patient receives this information at the time of discharge to include:
    - use and storage of the medication(s)
    - precautions and relevant warnings
    - importance of compliance with the directions

THIS BILL WOULD:

1. Require a pharmacist to include a large print informational insert with any prescription drug that poses substantial risk to the person when taken in combination with alcohol or other medications, including over-the-counter medications.
2. Specify that the insert must warn the patient of the specific risk involved.
3. Specify that a pharmacist cannot satisfy this requirement by referencing an outside source of information, such as an internet Web site.

4. Continue to require that a pharmacist, verbally and in writing, notify a patient if the drug may impair a person's ability to drive a motor vehicle.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor fiscal impact could be absorbed within existing board resources.

SUPPORT AND OPPOSITION:

COMMENTS:

This bill would require pharmacists to provide written information for medicine that interacts with alcohol, other prescription medicines or over-the-counter medicines. This is an expansion of the current requirement. Pharmacies may provide such written information sheets now. There is no mention what the source the pharmacist must consult to provide this information, e.g. Facts and Comparisons, Physician's Desk Reference, etc.

Typically, software vendors provide much of this written information in a form where pharmacists can provide it to the patient at the time of dispensing.

HISTORY:

2007
Mar. 22 Referred to Coms. on HEALTH and B. & P.
Feb. 23 From printer. May be heard in committee March 25.
Feb. 22 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 865 VERSION: As introduced February 22, 2007

AUTHOR: Davis SPONSOR: Author

RECOMMENDED POSITION: Neutral

SUBJECT: State agencies, live customer service agents

EXISTING LAW:

1. Requires each state agency to establish a procedure to ensure that incoming calls on any public line will be answered within 10 rings during regular business hours.

THIS BILL WOULD:

1. Require each state agency to answer telephone calls on any public line by a live customer service agent within 10 rings during regular business hours.

AUTHOR'S INTENT:

This legislation is to address the general frustration some constituents experience trying to access a live agent to speak with. Illinois enacted a similar requirement in 2005. The primary difference however is that the Illinois law allows for the use of an automated answering service, but must allow for a "zero-out" option.

FISCAL IMPACT:

Should this bill be enacted, the board will need to pursue a part-time office assistant to help assist board receptionists during peak calling times, e.g., Mondays, during renewal cycles etc.

COMMENTS:

The board's main public number is currently automated with the use of a phone tree. Callers are advised at the beginning of the recorded

message of the option to zero-out to speak with a board receptionist. This proposal would require the board to eliminate the use of the phone tree resulting in additional staff resources to respond to incoming calls. Because of limitations with the current phone system, staff is not aware of an new incoming call when the line is already in use.

The author's office indicates that there may be room to negotiate a requirement similar to the Illinois legislation.

HISTORY:

2007
Mar. 12 Referred to Com. on B. & P.
Feb. 23 From printer. May be heard in committee March 25.
Feb. 22 Read first time. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1025 VERSION: As introduced February 22, 2007

AUTHOR: Bass SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Professions and vocations: denial of licensure

EXISTING LAW:

1. Allows the board to deny a license on the grounds that an applicant has done any of the following:
   - Been convicted of a crime including a plead or verdict of guilty or a conviction following a plead of nolo contendere
   - Done any act involving dishonesty, fraud, deceit with the intent to substantially benefit himself or another, or substantially injure another
   - Done any act which if done by a licentiate of the business or profession in question would be grounds for suspension or revocation of a license
2. Prohibits the board from denying a license solely on the basis that he or she has been convicted of a felony if he or she has obtained a certification of rehabilitation or that he or she has been convicted of misdemeanor if he or she has met all applicable requirements of the criteria of rehabilitation as developed by the board
3. Allows the board to deny a license on the grounds that the applicant knowingly makes a false statement of fact required to be relevant in the application
4. Specifies the procedures the board must comply with to deny an application for licensure
5. Authorizes the board to suspend or revoke a license on the grounds that the licensee has been convicted of a crime if the crime is substantially related to the duties of the license
6. Details the board's requirement to notify the licensee of the revocation or suspension

THIS BILL WOULD:

1. Prohibit the board from denying an application based on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code (which means the court can dismiss the accusations or information against the defendant under certain circumstances.)
2. Prohibits the board from denying a license based on an arrest more than one year old if no disposition is reported.
3. Requires the board to include with a notice of denial a copy of the criminal record relied upon in making the denial determination.
4. Prohibit the board from suspending or revoking a license based on any criminal conviction that has been dismissed pursuant to Section 1203.4 or 1203.4a of the Penal Code.
5. Requires the board to send a copy of the criminal history record relied upon in making the determination to suspend or revoke the license to the ex-licensee.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board as criminal history records are already obtained as part of the investigation process.

COMMENTS:

Currently the board initiates disciplinary actions and may revoke, suspend or deny a license based on a conviction that is set aside if the conviction is substantially related to the license currently held, or being sought. However, the board does not provide a copy of the arrest report or criminal history record, although these documents may be referred to in the legal pleadings used to deny or revoke a license.

Staff is requesting clarification from counsel on the potential impact but is concerned that this proposal would limit the board's ability to pursue administrative action on violations that are substantially related to the practice of pharmacy.

HISTORY:

Mar. 12	Referred to Com. on B. & P.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 22	Read first time. To print.

Revised April 10, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1137 VERSION: As Amended March 27, 2007

AUTHOR: ENG SPONSOR: Author

RECOMMENDED POSITION: None

SUBJECT: Boards and Commissions

EXISTING LAW:

1. Defines the role of the Joint Committee on Boards, Commissions, and Consumer Protection, which is to evaluate whether a board or regulatory program has demonstrated a public need for the continued existence of the board or regulatory program.
2. Details the factors this committee shall consider including:
   - Whether regulation by the board is necessary to protect the public health, safety, and welfare
   - Whether the basis for the initial licensing of a practice or profession has changed
   - Whether other conditions have arisen that warrant an increase or decrease of the regulation
   - If regulation of the profession is necessary
   - Whether the board operates and enforces it regulatory responsibilities in the public's interest
   - Whether the board's operations indicate that the board performs its duties efficiently and effectively
   - Whether the composition of the board adequately represents the public interest and if the board encourages public participation in its decisions
   - Whether the board and its laws stimulate or restrict competition
   - Whether complaint, investigation and disciplinary procedures adequately protect the public
   - Whether the scope of practice of the regulated profession contributes to the highest utilization of personnel
   - Whether administrative and statutory changes are necessary to improve the board's operations to enhance the public interest.

THIS BILL WOULD:
Required the Committee to consider if the board's functions would be accomplished more effectively if the board were replaced by a single executive Officer.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS

SB 963 (Ridley-Thomas) would continue to require all boards to submit a Sunset Review report no later than 22 months before each board is slated to become inoperative; the report must detail among other items, the board's purpose, enforcement priorities, fund condition and legislative efforts to improve its legislative mandate. This bill would also remove the Department of Consumer Affairs (DCA) as the successor should the board become inoperative or is repealed.

FISCAL IMPACT:

The board does not anticipate any fiscal impact in providing additional information to the Joint Committee. However, should the Committee determine and recommend that the board's functions would be accomplished more effectively if the board were replaced by a single executive officer, there is a potential for fiscal impact.

HISTORY:

2007
Mar. 28 Re-referred to Com. on B. & P.
Mar. 27 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 26 Referred to Com. on B. & P.
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1276 VERSION: As introduced February 23, 2007

AUTHOR: Karnette SPONSOR: California Senior Legislature

RECOMMENDED POSITION: None

SUBJECT: Pharmacies: prescription labels: intended use

EXISTING LAW:

1. Details the labeling requirements for a prescription container to include, among other things, the condition for which the drug was prescribed, if it is requested by the patient.
2. Prohibits a pharmacist from dispensing a prescription medicine except in a container that meets the requirements of state and federal law.

THIS BILL WOULD:

1. Revise the labeling requirement to replace the condition for which the drug is prescribed with the intended purpose of the drug.
2. Require the authorized prescriber to ask a patient, or a patient's authorized representative whether to indicate the intended purpose of the prescription on the prescription label.
3. Exempt veterinarians from this new requirement.
4. Update references to recodified sections of pharmacy law.

AUTHOR'S INTENT

According to the California Senior Legislature, the sponsor of this bill, current law does not require the purpose of the medication to be written on the container and most patients are unaware of their right to make such a request to their doctor or pharmacist. Including the purpose for the prescription drug on the label will reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of the drug. It will also prevent patients from taking the wrong drug if they are not certain about the specific purpose of the medication. If someone is taking multiple medications, and there is no information

about the purpose of the drugs on the container, there is a potential for error and this bill is intended to eliminate or greatly reduce the risk of taking the wrong medication. The Veteran's Administration pharmacy in Sepulveda, California currently requires their physicians to include the purpose of the medication on all prescriptions.

PRIOR HISTORY/RELATED BILLS

AB 657 (Karnette) of 2005 – The bill died in the Senate. The board had a support position.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor impact could most likely be absorbed within existing resources.

COMMENTS:

This proposal appears to address the intent of a recommendation in the Medication Errors Panel Report, which requires that the intended use of the medication be included on all prescriptions.

HISTORY:

2007
Mar. 26 Referred to Coms. on HEALTH and B. & P.
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1399 VERSION: As introduced February 23, 2007

AUTHOR: Richardson SPONSOR: National Federation for the Blind

RECOMMENDED POSITION: None

SUBJECT: Pharmacies: prescription labels: assistive technology device

EXISTING LAW:

1. Details the labeling requirements for a prescription container.

THIS BILL WOULD:

1. Revise the labeling requirement to require, upon the request of a customer who is blind or visually impaired, a prescription label that is readable by an assistive technology device for such individuals. All Pharmacies would be required to comply with this section.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact. It is anticipated that any minor impact could be absorbed within existing resources.

COMMENTS:

The federal government has been looking at the issue since 2001. In 2005, the FDA submitted a report to the Senate Finance committee on this topic. We were unable to obtain a copy of this report.

We support the intent of this proposal because we agree that the label exists to assist patients with information on how to take their medication safely. However, we are concerned about the mandate that all

pharmacies acquire necessary equipment to accommodate the various devices consumers may use.

Staff identified at least three such devices that are available to assist blind or visually impaired individuals.

The Talking RX Prescription Accessory is a reusable digital recorder that attaches to the bottom of the most common sized prescription vials and allows for the recording of necessary medical and prescription information. This product retails for about $40.00.

The Aloud Audio Labeling System produced an audio version of a printed prescription label, which is then attached to the medication container. The consumer then uses an Aloud Player unit to replay the information recorded by the pharmacist.

The ScripTalk System works by the pharmacy software printing an auxiliary smart label using a dedicated, small-footprint printer. This smart label stores in the prescription information on the label. The consumer can hear the information by using a ScripTalk Reader.

HISTORY:

2007
Mar. 22 Referred to Com. on HEALTH.
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1587 VERSION: As introduced February 23, 2007

AUTHOR: De La Torre SPONSOR: Author

RECOMMENDED POSITION: None

SUBJECT: Personal information: pharmacy.

EXISTING LAW:

1. Defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product of service.
2. Details exemptions to the definition to include:
   - Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration
   - Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network.
   - Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about, among other things, treatment options. Such communications may result in direct or indirect remuneration if the individual receiving the communication is notified of such, in a typeface no smaller that 14-point font.

THIS BILL WOULD:

1. Also exempt a written communication or message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, if all of the following apply:
   - The communication does not involve the sale or transfer of individually identifiable patient information
   - The communication assists the pharmacist or pharmacy personnel in the transmittal of use information regarding a prescription drug dispensed to the patient
   - The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease

or health condition for which the drug is dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient.

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type.
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for.

AUTHOR'S INTENT

This bill is intended to clarify the existing statute and would exempt drug information from the definition of "marketing communications."

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor impact could most likely be absorbed with existing resources.

HISTORY:

2007
Mar. 29 Referred to Com. on HEALTH.
Feb. 26 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 23 Introduced. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 472 VERSION: As amended April 9, 2007

AUTHOR: Richardson SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Pharmacies: prescription labels

EXISTING LAW:

1. Details the labeling requirements for a prescription container.
2. Prohibits a pharmacist from dispensing a prescription that does not meet the labeling requirements

THIS BILL WOULD:

1. Makes findings about the cost of health care and prescription drugs
2. Makes findings about the number of medication errors and sites some causes for these errors.
3. States that it is the intent of the Legislature to adopt a standard format for the labeling of prescription drug containers dispensed in this state, to include a regulation for the font size of printed words, the placement of the information of the prescription as well as translated prescription drug labels for a patient whose primary language is not English.
4. Create a prescription drug label panel and specify the membership of the panel.
5. State that the panel shall be appointed to work with the board and/or board staff.
6. Require that the panel advise the board on the development of a standardized prescription label for prescription drug containers to ensure the label
   - Is readable to consumers
   - Describes the contents of the container so that consumers with a 4th grade reading level can understand

- Displays necessary information about properly taking the medication so that consumers with a 4th grade reading level can understand
- Displays mandated warnings in so that consumers with a 4th grade reading level can understand

7. Require that a translation of the information can be obtained at the pharmacy
8. Require that the panel ensure the recommendations are affordable to independent pharmacies
9. The panel must begin meetings on or after January 1, 2008.
10. Require the board to adopt a standardized prescription label on or before September 30, 2008 and shall report the finding to the appropriate committees of the Legislature.
11. Require all instate pharmacies to begin using the standardized label on or after January 1, 2009.

AUTHOR'S INTENT:

To create a standardized prescription label.

FISCAL IMPACT:

The board anticipates a significant fiscal impact on existing resources if required to facilitate and sponsor all panel meetings.

COMMENTS:

This proposal appears to address recommendations made in the Medication Error Panel Report.

HISTORY:

2007

Apr. 9 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on RLS. Re-referred to Com. on B.,P. & E.D. Set for hearing April 23.
Feb. 28 To Com. on RLS.
Feb. 22 From print. May be acted upon on or after March 24.
Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 615 VERSION: As amended March 27, 2007

AUTHOR: Oropeza SPONSOR: The Latino Coalition for a Healthy California

RECOMMENDED POSITION: None

SUBJECT: Pharmacy technicians: scholarship and loan repayment program.

EXISTING LAW:

1. Defines the requirements for licensure as a pharmacy technician.

THIS BILL WOULD:

1. Establish a scholarship and loan repayment program for pharmacy technicians.
2. Requires all licensed pharmacy technicians and pharmacies to pay an additional $10.00 to this account at the time of renewal.

AUTHOR'S INTENT

This bill is intended to provide a financial incentive to recruit more individuals to become pharmacy technicians to assist in medically underserved areas. US Bureau of Labor statistics detail a shortage of technicians from different cultural backgrounds.

FISCAL IMPACT:

The cost associated with the development and implementation of this fund could include modifications to existing cashiering programs, forms and procedures for deposits into separate funds. However, these costs would be covered by the board's prorata to the Department.

SUPPORT AND OPPOSITION:

COMMENTS:

As amended this legislation will require all pharmacy technicians and pharmacies to contribute $10.00 to the Pharmacy Technician Scholarship and Loan Repayment Program Fund at renewal. The language at introduced created the scholarship fund, but did not include a mandatory contribution to the fund, rather made the contribution voluntary.

This proposal is similar to one passed in 2002, which established a scholarship and loan repayment fund for pharmacists. To date, no funds have been distributed from this fund, as the minimum account balance of $200,000 annually has not yet been obtained. The board was coincidentally doing a newsletter article updating licensees about the status of this law and learned that to date, pharmacies and pharmacists have contributed approximately $38,000.

Current statutes detail the licensing requirements for technicians to include:

- Completion of a technician training program
- AA degree in pharmacy technology
- Satisfy requirements for RPH exam
- Certification by the Pharmacy Technician Certification Boards.

This proposal would only assist those applicants who qualify based on the training program or pharmacy technology.

The Licensing Committee recently discussed the qualification methods for pharmacy technicians and will be continuing their discussion about the possible enhancement/standardization of the minimum qualifications.

HISTORY:

2007
Mar. 27 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on HEALTH.
Mar. 15 Set for hearing April 11.
Mar. 13 Withdrawn from committee. Re-referred to Coms. on HEALTH and B., P.& E.D.
Mar. 8 To Coms. on B., P. & E.D. and HEALTH.
Feb. 23 From print. May be acted upon on or after March 25.

Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Revised April 10, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 809 VERSION: As Amended March 26, 2007

AUTHOR: Ashburn and Runner SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Nurse practitioners: scope of practice.

EXISTING LAW:

1. Defines the scope of practice for nurse practitioners
2. Allows a nurse practitioner to dispense drugs pursuant to a protocol and specifies the conditions under which this can be done
3. Requires the Board of Registered Nursing to establish categories of nurse practitioners and standards for nurses to hold themselves out as nurse practitioners
4. Details the requirements for a certificate evidencing that a person is qualified as a nurse practitioner
5. Specifies the information required on a written order for a prescriber

THIS BILL WOULD:

1. Expand the scope of practice for a nurse practitioner to include:
   - Perform a comprehensive history and physical examination
   - Establish diagnoses for physical, mental or emotional ailments or potential ailments
   - Admit patients to hospitals and nursing facilities
   - Order, perform and interpret laboratory, radiographic and other diagnostic tests
   - Identify, develop, implement and evaluate a plan of care for a patient to promote, maintain and restore health
   - Perform therapeutic procedures to ensure that the nurse practitioner is qualified by education and experience to perform
   - Prescribe treatments
   - Prescribe and dispense medications when granted authority by the Board of Registered Nursing
   - Refer patients to appropriate licensed physicians and surgeons or other health care providers
   - Provide emergency care
   - Perform additional acts that the nurse practitioner is educationally prepared for and clinically competent to perform

- Sign death certificates, return-to-work, school certificates and other related health certification forms
- Sign handicapped parking applications
- Order home health services
- Order durable medical equipment

2. Independently Prescribe Schedule II through Schedule V controlled substances
3. Prohibit a nurse practitioner from prescribing drugs or devices unless the Board of Registered Nursing has certified that a nurse practitioner has completed at least six months of supervised experience in the prescribing of drugs and devices
4. Require a nurse practitioner to register with the US DEA
5. Remove the reference to the protocol requirement for naturopathic doctors
6. Update Business and Professions Code section 4024(a) to include nurse practitioner
7. Update Business and Professions Code section 4040 (a)(2) to include nurse practitioner
8. Update Business and Professions Code section 4060 to allow a nurse practitioner to possess a controlled substance
9. Update Business and Professions Code section 4061 to allow a nurse practitioner to obtain samples
10. Update Business and Professions Code section 4170 to include a licensed or certification as a nurse practitioner who is registered by the Board of Registered Nursing
11. Remove all references to a nurse practitioner performing duties pursuant to a protocol

AUTHOR'S INTENT

According to the author's office, this proposal is to allow a nurse practitioner to independently run clinics. This will help to increase access to healthcare in rural communities.

PRIOR HISTORY/RELATED BILLS

FISCAL IMPACT:

The Board of Pharmacy does not anticipate any significant fiscal impact.

COMMENTS

This bill was significantly amended on March 26, 2007.

HISTORY:

2007

Mar. 29 Set for hearing April 23.
Mar. 29 Re-referred to Com. on B., P. & E.D.
Mar. 26 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 8 To Com. on RLS.
Feb. 26 Read first time.
Feb. 24 From print. May be acted upon on or after March 26.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.
Feb. 24 From print. May be acted upon on or after March 26.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 822 VERSION: As Amended March 28, 2007

AUTHOR: Aanestad SPONSOR: California Psychological Assoc. & American Federation of State, County and Municipal Employees

RECOMMENDED POSITION: Oppose Unless Amended

SUBJECT: Psychology

EXISTING LAW:

1. Defines the scope of practice for psychologists.
2. Defines a prescription and includes that if it is in writing, must be signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistance, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1 or 3640.5, or the pharmacist who issues a drug order pursuant to the scope of practice defined.
3. Specifies the information required on a written order for a prescriber.

THIS BILL WOULD:

1. Make several legislative findings and declarations including, but not limited to :
- One in four individuals suffer from a diagnosable mental illness
- There are 11 counties with no psychiatrists and 17 additional counties with five or fewer psychiatrists
- 80% of all psychotropic drug prescriptions are written by nonpsychiatrists with limited training in mental health.
- Californians living in rural areas are underserved by health care practitioners.

2. State that it is the intent of the Legislature to support a program whereby psychologists who choose to receive the appropriate education and training may prescribe medications for their patients.
3. Authorize the Board of Psychology to establish and administer a certification process to grant psychologists prescription authority as well as develop procedures for psychologists-in-training to prescribe under the supervision and licensed of a qualified prescriber.
4. Defines prescriptive authority as the authority to prescribe, discontinue, order, administer or dispense without charge, drugs or controlled substances recognized for or used in the inpatient or outpatient diagnosis,

treatment or evaluation and management of individuals with psychiatric, mental, cognitive, nervous, emotional, addictive, developmental, or behavioral disorders in conformance with the rules and regulations adopted by the Board of Psychologists.

5. Define the requirements for a "health service provider"
6. Define a prescribing psychologist as a health service provider who has received a valid certificate granting prescriptive authority.
7. Establish requirements for a prescribing psychologist to include a Master's degree in psychopharmacology, training from an approved provider of continuing education that has been approved by the board or other coursework that is consistent with the guidelines of the American Psychological Association (APA). The board may waive this requirement in its discretion under certain circumstances.
8. Establish the requirement for supervised clinical experience to obtain competency in prescribing and in psychopharmacological treatment of a diverse patient population under the direction of qualified prescribers as described.
9. Detail the recordkeeping requirements for a prescribing psychologist.
10. Require the Board of Psychology to annually transmit a list of prescribing Psychologists to the Board of Pharmacy as well as provide prompt updates to the list provided.
11. Update Business and Professions Code section 4040 to include prescribing psychologists as an authorized prescriber.
12. Changes (a)(1)(F) to use the term "health care practictioner" and strikes out all other licensees referenced except prescriber.
13. Allow for more than one patient on a written order.
14. Prohibit a prescribing psychologist from prescribing medications other than those generally recognized for treatment of disorders within the scope of practice of a psychologist.
15. Allow a psychiatric technician, working in a mental health facility to administer medications prescribed by a prescribing psychologist.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS

SB 993 (Calderon) also deals with the scope of practice for psychologists. The intent of this legislation to increase access to prescription drugs to treat mental health conditions my appropriately trained and licensed professionals.

FISCAL IMPACT:

Should the board be required to maintain the list of prescribing psychologists for pharmacists to reference the board could incur fiscal impact.

COMMENTS

This bill was significantly amended on March 28, 2007 and has expanded from the initial scope of the introduced legislation.

It is unclear under what circumstances it would be appropriate for a prescriber to write a single prescription for multiple patients on one prescription form that is not already covered in law.

It is also unclear what the intent is behind the changes to 4040(a)(1)(F). Staff was unable to identify a meaning of health care practitioner and is concerned that this change could inadvertently change of requirements under which several licensees, including a certified nurse-midwife, nurse practitioner, physician assistant or naturopathic doctor or pharmacist could issue a drug order. This provision will need to be restored.

This proposal requires the Board of Psychology to provide the board with a list of the prescribing psychologists, but does not provide the Board of Pharmacy with information or directions on what this list is to be used for. If the intent of this requirement to is to maintain a list of such prescribing psychologists that is readily retrievable for pharmacists, this should be maintained and disseminated by the Board of Psychology.

HISTORY:

2007
Mar. 28 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 8 To Com. on RLS.
Feb. 26 Read first time.
Feb. 24 From print. May be acted upon on or after March 26.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 963 VERSION: As introduced February 23, 2007

AUTHOR: Ridley-Thomas SPONSOR: BP& ED Committee

RECOMMENDED POSITION: None

SUBJECT: Regulatory boards: termination

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Continue to require all boards to submit a Sunset Review report no later than 22 months before each board is slated to shall become inoperative; the report must detail among other items, the board's purpose, enforcement priorities, fund condition and legislative efforts to improve its legislative mandate.
2. Remove the DCA as the successor should the board become inoperative or is repealed.

AUTHOR'S INTENT

According to the author's office, the intent of this legislation is to determine or redefine the sunset review process. It is anticipated that the bill language will be amended in mid-April, in advance of the policy committee meeting.

FISCAL IMPACT:

It is difficult to anticipate the fiscal impact of this legislation until the full scope of the changes are documented.

COMMENTS:

This legislation does not release the board from the Sunset Review process, whereby the board's report will be due to the Legislature no later than May 2008.. This bill is silent on what agency, if any, would succeed the board with all the powers, purpose, responsibilities and jurisdiction not otherwise repealed.

HISTORY:

2007
Mar. 29 Set for hearing April 23.
Mar. 15 To Com. on B., P. & E.D.
Feb. 26 Read first time.
Feb. 25 From print. May be acted upon on or after March 27.
Feb. 23 Introduced. To Com. on RLS. for assignment. To print.

Revised March 26, 2007

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 966 VERSION: As introduced February 23, 2007

AUTHOR: Simitian and Kuehl SPONSOR: Constituent

RECOMMENDED POSITION: None

SUBJECT: Pharmaceutical drug disposal

EXISTING LAW:

1. Existing law is silent on how a consumer should dispose of unused medication.

THIS BILL WOULD:

1. Make findings and declarations related to the presence of prescription and non prescription drugs in streams and the negative effects on fish and other aquatic species.
2. Discuss the potential impact this may have on human health.
3. Establish a program through which the public may return and ensure the safe and environmentally sound disposal of prescription drugs.
4. Define "consumer", "pharmaceutical drug", "retailer", and "sale."
5. Require on or after July 1, 2008, that every retailer shall have a system to accept pharmaceutical drugs for proper disposal.
6. Require the system to:
   - Be at no cost to the consumer if it is the type or brand which the retailer sold previously
   - Provide a notice to consumers that provides consumers access to obtain more information about opportunities and locations for no-cost pharmaceutical drug recycling
   - Provide information about the retailer's pharmaceutical drug return opportunities
7. Make it unlawful for a retailer to sell a pharmaceutical drug to a consumer unless the retailer is in compliance with these requirements.

8. States that any person who violates this section, if convicted, be subject to imprisonment and/or a fine of up to ($1,000.)

AUTHOR'S INTENT

This bill was introduced upon recommendation of a constituent. The language is modeled after a similar bill that defined a dry cell batter as a household waste and requires retailers to accept these back to ensure appropriate disposal.

The intent of this legislation is to classify over-the-counter and prescription drugs as household waste as well as to require pharmacy retailers to accept such returned household waste for proper disposal.

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board.

COMMENTS:

We recognize the need for the intent of this legislation, but are concerned that the appropriate balance is not achievable given the language of the bill as introduced.

The author's office has been in contact with the board and appears willing to accept amendments that could potentially ease the burden on pharmacies, without compromising the intent of the legislation.

The board's Enforcement Committee recently heard concern from a representative of Omnicare who stated that the return of prescription drugs from patients in Long Term Care is problematic as no mechanism is in place to allow for this to occur. Absent any regulation, there is no safeguard to ensure that the returned medications will not be diverted.

HISTORY:

2007

Mar. 19	Set for hearing March 26.
Mar. 15	To Coms. on E.Q.; B.P. & E.D.; and RLS.
Feb. 26	Read first time.
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 23	Introduced. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 993 VERSION: As introduced February 23, 2007

AUTHOR: Calderon SPONSOR:

RECOMMENDED POSITION: None

SUBJECT: Psychologists: scope of practice: prescribing drugs

EXISTING LAW:

1. Defines the scope of practice for psychologists

THIS BILL WOULD:

1. Makes several legislative findings and declarations including, but not limited to :
   Psychologists with appropriate credentials have been allowed to prescribe medication to active duty personnel.
   Louisiana and New Mexico are two states that have adopted legislation to allow authorizing prescriptive authority for psychologists
   For years psychologists in California have been allowed to discuss and recommend psychotropic medication s to both patients and physicians.
   California licensed psychologists complete an average of seven years of postbaccalaureate study and 3000 hours of postgraduate supervised practice in the diagnosis and treatment of mental illness.
   Research data demonstrates that there is not enough mental health care available to serve the needs of all people in California due to the shortage of psychiatrists
   Professional psychology has developed a model curriculum for the education and training of prescribing psychologists.
2. Allow for the prescribing of drugs authorized pursuant to Article 1.5
3. Create Article 1.5 – Prescription Certificate and Conditional Prescription Certificate.

4. Defines a "prescribing mental health professional" as a medically trained and licensed physician, psychiatrist, advance practice nurse or nurse practitioner specializing in mental health
5. Allows a psychologist to apply for a conditional prescription certificate from the Board of Psychology if all of the following conditions are met
    - Holds a current license in good standing to practice psychology in this state
    - Has successfully completed a planned sequence of psychopharmacological training from an institution of higher learning approved by the Board of Psychology or satisfies other education requirements
    - Has passed a national proficiency examination approved by the Board of Psychology that tests the applicant's knowledge of pharmacology in the diagnosis, care and treatment of mental disorders
    - Applies for a DEA license for limited use restricted by the state
    - Meets other requirements as determined by rules adopted by the Board of Psychology.
6. Allows a psychologist holding a conditional prescription certificate to administer and prescribe psychotropic medications within the recognized scope of the profession, including the ordering and review of laboratory tests in conjunction with prescribing medication for the treatment of mental disorders.
7. Require the psychologist holding a conditional prescription certificate to maintain an ongoing collaborative relationship with the medical practitioner who oversees the patient's general medical care
8. Details the requirements for a prescription written by a psychologist with a conditional prescription certificate
9. Allows a psychologist to apply for a prescription certificate from the Board of Psychology if the applicant:
    - Has been issued a conditional prescription certificate and has successfully completed one year of prescribing of psychotropic medications
    - Holds a current license to practice psychology in California
    - Meets all other requirements adopted by the Board of Psychology
10. Allows a psychologist with a prescription certificate to prescribe psychotropic medication is all of the following conditions are met:
    - Continues to hold a current license to practice psychology in California

- Complies with requirements
- Annually satisfies the continuing education requirements for psychologists

11. Requires the board to adopt rules to establish the procedures to obtain a conditional prescriptive certificate, prescriptive certificate and renewal of such certificates
12. Requires the board to adopt rules to pursue administrative action against applicants and licensees
13. Require the Board of Psychology to provide the Board of Pharmacy with an annual list of psychologists holding a conditional prescription certificate
14. States that the Board of Psychology is the sole and exclusive administrative body to implement and oversee this article.
15. Does not allow permit a medical psychologist to administer or prescribe a narcotic
16. Details other individuals with which this article does not apply.

AUTHOR'S INTENT

The board is awaiting a response from the author's office.

FISCAL IMPACT:

Should the Board of Pharmacy be required to maintain the list of prescribing psychologists for pharmacists to reference the board could incur a fiscal impact.

COMMENTS:

This bill is similar to SB 822. It is our understanding that these two proposals will most likely merge into one.

HISTORY:

2007
Mar. 29 Set for hearing April 23.
Mar. 15 To Com. on B., P. & E.D.
Feb. 26 Read first time.
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